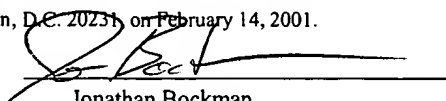


DAC.

PATENT
Docket No. 229752000600

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Assistant Commissioner for Patents, Washington, D.C. 20231, on February 14, 2001.


Jonathan Bockman

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Alan G. BAXTER

Serial No.: 09/308,192

Filing Date: July 14, 1999

For: MYCOBACTERIUM CELL WALL
COMPOSITIONS

Examiner: Li Lee

Group Art Unit: 1645

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**PETITION UNDER 37 CFR 1.181 FOR WITHDRAWAL
OF RESTRICTION REQUIREMENT**

Commissioner for Patents
Washington, D.C. 20231

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OFFICE OF PETITIONS

Sir:

Applicant petitions under 37 CFR 1.181 for review of the restriction requirement made final in the Office Action dated December 14, 2000. No fee is required for this petition.

Applicant requests that the restriction requirement be overturned in view of the arguments made in the response to the restriction requirement filed on September 25, 2000, and further in view of the following discussion.

Statement of Facts

The Examiner imposed an election/restriction requirement in an Action dated July 25, 2000, stating that the application contained six different inventions that did not relate to a single inventive concept under PCT Rule 13.1. The Examiner admitted that groups I-VI were related in that they all concern the use of *Mycobacterium* cell wall components for immunomodulatory therapy. However, the Examiner contended that Groups I-VI did not relate to a single inventive concept since *Adams et al.* U.S. Patent No. 4,52,423 allegedly teaches “a method of immunomodulatory therapy in a mammal comprising administering a component of the cell wall of *Mycobacterium*.” The Examiner contended that since *Adams* teaches the linking concept, the identified concept could not be a single inventive concept under PCT Rule 13.1.

On September 25, 2001, Applicant filed a response to the restriction requirement, electing the claims of group I with traverse. Applicant argued that the claims of groups I-VI all pertained to a single inventive concept related to “methods of immunomodulatory therapy using cell wall components of *Mycobacterium* or a related organism or analogous components from another biological source or chemical equivalents of said components.” Applicant further argued that the restriction requirement concerning Groups I and II, which contain overlapping sets of claims, should be withdrawn.

On December 14, 2000, the Examiner made the restriction requirement final in the first Office Action on the merits. The Examiner again argued that the technical feature of using *Mycobacterium* cell wall components was covered by *Adams* and could thus not qualify as a special technical feature as defined by PCT Rule 13.2 because *Adams* teaches “a method of immunomodulatory therapy in a mammal comprising administering a component of the cell wall of *Mycobacterium*.” The Examiner then reviewed the claims in group I on the merits, rejecting them as anticipated under 35 USC 102(b) by *Robinson et al.*, J. Clin. Lab. Immunol. 24(4), 171-6, 1987, which, in the Examiner’s view, teaches “a method of immunomodulatory therapy in a human comprising administering the components of cell wall *Mycobacterium*.”

Analysis

The Examiner's argument is inherently contradictory. If Adams shows what the Examiner contends it does, then it should have been used to reject the claims. Instead, Adams was not even cited as being of interest on a Form PTO-892. The failure to cite Adams even as being of interest thus signifies that the Examiner did not rely on Robinson instead of Adams because it was better art than Adams; instead, the Examiner has tacitly recognized that Adams is not factually sufficient to support the Examiner's view that the linking inventive concept of applicant's claims was known in the prior art. Therefore, the Examiner's action on the merits destroys the factual basis on which the restriction requirement rests and demonstrates that it should be reversed as not being supported by the evidence.

Restriction requirements are used to make sure that only a single invention or inventive concept is claimed in each patent application and are separate from office actions on the merits. Thus, restriction practice under PCT Rule 13.2 and 37 CFR 1.475(a) does not involve actually deciding questions of patentability over the prior art on the merits, but is only a preliminary inquiry designed to decide minimally whether unity of invention exists. In this application, the Examiner has misapplied the restriction rules to produce a prior art rejection on the merits and then has turned around and not even cited the reference used to support the restriction decision.. Applicant thus has to overcome a prior art rejection twice, once in the restriction phase and one on the merits, meaning that the restriction effectively accomplished nothing. As such, the Examiner's faulty application of the rules constitutes a reversible abuse of discretion.

Finally, the Examiner has identified claims 1-4, 7-10, 20, and 21 as belonging to Group I and claims 1, 5-10, 20, and 22 as belonging to Group II. Claims 1, 7-10, and 20 thus belong to both Groups. The Examiner has provided no evidence or rationale to support a holding that claims 1, 7-10, and 20 each embrace multiple inventions. The Examiner's reasoning can only be

used to create groups of claims in this application that are mutually exclusive. Therefore, there is no basis for setting the claims in common between Groups I and II in more than one group.

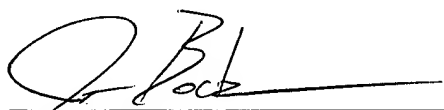
For the foregoing reasons Applicant requests that the restriction requirement be reversed and that all claims in the application be examined together. Alternatively, at least the claims of Groups I and II, which include many of the same claims, should be examined together.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR 1.16 and 1.17 that may be required by this petition, or to credit any overpayment, to **Deposit Account No. 03-1952**, Ref. 229752000600. A duplicate copy of this petition is enclosed.

Respectfully submitted,

Dated: February 14, 2001

By:



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Registration No. 45,640

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